

12-14-04

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DOCKET NO. CELL0001-106

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Hart et al.

Confirmation No. 3465

Serial No.: 10/766,718

Art Unit: 1644

Filing Date: January 27, 2004

Examiner: Not Yet Assigned

For: INHIBITION OF INTIMAL HYPERPLASIA USING ANTIBODIES TO PDGF RECEPTORS

Customer No.: 34133

EXPRESS MAIL NO.: EL964 552 831US  
DATE OF DEPOSIT: December 13, 2004

MAIL STOP AMENDMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ before the mailing date of a first Office Action on the merits.

- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☒ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of non-U.S. Patent references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed herewith

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of references @@@, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☒ Copies of references AA-AC, AF-AI, AK, AM, AX, AZ, BA, BD, BE, BG-BJ, BM, BN, BR, BT and BW, listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and

Trademark Office in prior application **Serial No. 09/265,116**, filed on **March 9, 1999**, abandoned.

☒ Copies of references **AA-AC, AL, AX, AZ, BA, BC-BF, BI, BM, BT, BW**, listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in prior application **Serial No. 08/023,504**, filed on **February 25, 1993**, abandoned.

☒ Copy of reference **BH** listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 was previously cited by or submitted to the U.S. Patent and Trademark Office in prior application **Serial No. 08/304,623**, filed on **September 12, 1994**, abandoned.

☒ Copies of references **AA, AB, AD, AE, AJ-AN, AQ-AU, AW-AZ, BA, BB, BE-BG, BH, BJ-N, BT, BU and BW**, listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in prior application **Serial No. 08/366,860**, filed on **December 30, 1994**, now **U.S. Patent No. 5,620,687**.

☒ Copies of references **AD, AE, AJ, AM, AN, AP-AZ, BA, BB, BG, BH, BJ-BL, BO-BV**, listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in prior application **Serial No. 08/482,533**, filed on **June 7, 1995**, now **U.S. Patent No. 5,976,534**.

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Pursuant to Fed. Reg. Vol. 69, No. 182, dated September 21, 2004, copies of U.S. Patents and U.S. Patent Publications need not be submitted as part of an Information Disclosure Statement.

**Statement under 37 C.F.R. § 1.704(d)**

☐ The undersigned attorney hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than 30 days prior to the filing of the Information Disclosure Statement.

**Petition**

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.


**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$ \_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$ \_\_\_\_\_. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

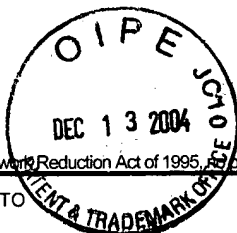
There are no listed references, which are not in the English language.

Respectfully submitted,

Dated: December 13, 2004

  
**Doreen Yatko Trujillo**  
**Registration No. 35,719**

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 5

**Complete if Known**

Application Number	10/766,718
Filing Date	January 27, 2004
First Named Inventor	Charles E. Hart et al.
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	CELL0001-106

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	AA	US- 5,094,941	03/10/1992	Hart	
	AB	US- 5,155,027	10/13/1992	Sledziewski et al.	
	AC	US- 5,171,217	12/15/1992	March et al.	
	AD	US- 5,250,519	10/05/1993	Conrad et al.	
	AE	US- 5,268,358	12/07/1993	Fretto	
	AF	US- 5,468,468	11/21/1995	LaRochelle et al.	
	AG	US- 5,620,087	04/15/1997	Hart et al.	
	AH	US- 5,817,310	10/06/1998	Ramakrishnan et al.	
	AI	US- 5,882,644	03/16/1999	Chang et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	AJ	EP 0 568 310	11/03/1993			Yes
	AK	WO 92/13867	08/20/1992	COR Therapeutics, Inc.		Yes
	AL	WO 92/20642	11/26/1992	Rhone Poulenc Rorer Int.		Yes
	AM	WO 93/10805	06/10/1993	COR Therapeutics, Inc.		Yes
	AN	WO 94/16706	08/04/1994	Neorx Corp.		Yes
	AO	WO 94/21689	09/29/1994	Cancer Res Campaign Tech		Yes

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 5

**Complete if Known**

Application Number	10/766,718
Filing Date	January 27, 2004
First Named Inventor	Charles E. Hart et al.
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	CELL0001-106

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AP	BERK, B.C., ET AL., "Pharmacologic roles of heparin and glucocorticoids to prevent restenosis after coronary angioplasty," <i>JACC</i> , 17(6):111B-117B, (1991)	
	AQ	<i>BioWorld Today</i> , 5(4):1 and 3, (1994)	
	AR	BUCHWALD, A.B., ET AL., "Low-molecular-weight heparin reduces neointimal proliferation after coronary stent implantation in hypercholesterolemic minipigs," <i>Circulation Research</i> , 86(2):531-537, (1992)	
	AS	CASTELLOT, J.J., ET AL., "Progression in calf aortic smooth muscle cells," <i>J. Cell Biol.</i> , 109(6):3147-3155, (1989)	
	AT	CAVARI, S., ET AL., "Effects of heparin on normally transformed NIH/Microblasts," <i>Cell Bio. Int'l</i> , 17(8):781-786, (1993)	
	AU	CLOWES, A.W., ET AL., "Kinetics of cellular proliferation after arterial injury," <i>Circulation Research</i> , 58(6):839-845, (1986)	
	AV	CLOWES, A.W., "Heparin: Will it control intimal thickening after angioplasty," <i>Circulation Research</i> , 86(5):1657-1658, (1992)	
	AW	CURRIER, J.W., ET AL., "Low molecular weight heparin (Enoxaparin) reduces restenosis after iliac angioplasty in the hypercholesterolemic rabbit," <i>JACC</i> , 17(6):118B-125B, (1991)	
	AX	DeFEUDIS, F.V., "PDGF antibody and restenosis," <i>DN&amp;P</i> , 5(1):49-51, (1992)	
	AY	EDELMAN, E.R., ET AL., "Effect of controlled adventitial heparin delivery on smooth muscle cell proliferation following endothelial injury," <i>Proc. Natl. Acad. Sci. USA</i> , 87:3773-3777, (1990)	
	AZ	FERNS, G.A.A., ET AL., "Inhibition of neointimal smooth muscle accumulation after angioplasty by an antibody to PDGF," <i>Science</i> , 253:1129-1132, (1991)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 5

**Complete if Known**

Application Number	10766,718
Filing Date	January 27, 2004
First Named Inventor	Charles E. Hart et al.
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	CELL0001-106

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BA	FERRELL M., ET AL., "Choosing appropriate experimental animal model for the prevention of restenosis," <i>Circulation Research</i> , 85(4):1630-1631, (1992)	
	BB	GUYTON, J.R., ET AL., "Inhibition of rat arterial smooth muscle cell proliferation by heparin," <i>Circulation Research</i> , 46(5):625-634, (1980)	
	BC	HARKER, L.A., "Role of platelets and thrombosis in mechanisms of acute occlusion and restenosis after angioplasty," <i>Am. J. Cardiol.</i> , 60:20B-28B, (1987)	
	BD	HARRIS, ET AL., "Therapeutic antibodies-the coming of age," <i>Tibtech</i> , 11:42-44, (1993)	
	BE	HART, C.E., ET AL., "Synthesis, phosphorylation, and degradation of multiple forms of the platelet-derived growth factor receptor studied using a monoclonal antibody," <i>J. Biol. Chem.</i> , 262:10780-10785, (1987)	
	BF	HIRD, V., ET AL., "Immunotherapy with monoclonal antibodies," <i>Genes and Cancer</i> , 183-189, (1990)	
	BG	JAWIEN, A., ET AL., "Platelet-derived growth factor promotes smooth muscle migration and intimal thickening in a rat model of balloon angioplasty," <i>J. Clin. Invest.</i> , 89:507-511, (1992)	
	BH	KAWAHARA, R.S., ET AL., "Monoclonal antibody C3.1 is a platelet derived growth factor (PDGF) antagonist," <i>Biochem. Biophys. Res. Commun.</i> , 147:839-845, (1987)	
	BI	KELLY, J.D., ET AL., "Platelet-derived growth factor (PDGF) stimulates PDGF receptor subunit dimerization and intersubunit trans-Phosphorylation," <i>J. Biol. Chem.</i> , 266:8987-8992, (1991)	
	BJ	KIMURA, I., ET AL., "Platelet-derived growth factor (PDGF) accelerated induction of competence, and heparin does not inhibit PDGF-induced competence in primary cultured smooth muscle cells of rat aorta," <i>Japan J. Pharmacol.</i> , 59:51-56, (1992)	
	BK	LINDNER, V., ET AL., "Basic fibroblast growth factor stimulates endothelial regrowth and proliferation in denuded arteries," <i>J. Clin. Invest.</i> , 85:2004-2008, (1990)	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/766,718
		Filing Date	January 27, 2004
		First Named Inventor	Charles E. Hart et al.
		Art Unit	1644
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	CELL0001-106
Sheet	4	of	5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BL	LINDNER, V., ET AL., "Inhibition of smooth muscle cell proliferation in injured rat arteries," <i>J. Clin. Invest.</i> , 90:2044-2049, (1992)	
	BM	MAJESKY, M.W., ET AL., "PDGF ligand and receptor gene expression during repair of arterial injury," <i>J. Cell. Biol.</i> , 111:2149-2158, (1990)	
	BN	MULLINS, D.E., ET AL. "Inhibition of PDGF receptor binding and PDGF-stimulated biological activity in vitro and of intimal lesion formation in vivo by 2-bromomethyl-5-chlorobenzene sulfonylphthalimide," <i>Arterioscler Thromb.</i> , 14:1047-1055, (1994)	
	BO	POPMA, J.J., ET AL., "Clinical trails of restenosis after coronary angioplasty," <i>Circulation Research</i> , 84(3):1426-1436, (1991)	
	BP	PREISACK, M.B., ET AL., "Experimental and early clinical experience with reviparin-sodium for prevention of restenosis after percutaneous transluminal coronary angioplasty," <i>Blood Coagulation and Fibrinolysis</i> , 4(1):S55-S58, (1993)	
	BQ	PREISACK, M.B., ET AL., "The paradigm of restenosis following percutaneous transluminal coronary angioplasty," <i>Euro. Heart. Jrl.</i> , 14(1):187-192, (1993)	
	BR	RAMAKRISHNAN., ET AL., <i>Growth Factors</i> , 8:253-265, (1993)	
	BS	REILLY C.F., ET AL., "Heparin-like molecules regulate the number of epidermal growth factor receptors on vascular smooth muscle cells," <i>J. Cell Phys.</i> , 136:23-32, (1988)	
	BT	RUBIN, K., ET AL., "Induction of b-type receptors for platelet-derived growth factor in vascular inflammation: possible implications for development of vascular proliferative lesions," <i>The Lancet</i> 1(8599):1353-1356, (1988)	
	BU	SCHMID, K.M., ET AL., "First clinical experience with low molecular weight heparin LU 47311 (Reviparin) for prevention of restenosis after percutaneous transluminal coronary angioplasty," <i>Seminars in Thrombosis and Hemostasis.</i> , 19 Suppl., 155-159, (1993)	
	BV	VIOLARIS, A.G., ET AL., "Heparin in coronary artery disease: new uses for an old drug," <i>British Jrl. of Hosp. Med.</i> , 49(1):37-43, (1993)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10766,718
				Filing Date	January 27, 2004
				First Named Inventor	Charles E. Hart et al.
				Art Unit	1644
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	CELL0001-106
Sheet	5	of	5		

[illegible]

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1. Applicant's unique citation designation number (optional). 2. Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*